IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/075053	Confirmation No. 8092
Applicant	:	Robert C. Stevens	
Filed	:	February 13, 2002	
TC/A.U.	:	3767	
Examiner	:	Bhisma Mehta	
Title	:	REINFORCED CATHETER DEVICE, CATHETER STOCK, AND METHODS AND APPARATUS FOR MAKING SAME	
Docket No.	:	ANG-17553	
Customer No.	:	040854	

REPLY BRIEF
(37 C.F.R. §41.41)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Reply Brief is filed in response to the Examiner's Answer mailed on November 30, 2007 in connection with the above-identified patent application on appeal. Under 37 CFR 41.41(a)(1) and 41.43(b) appellant may file a Reply Brief as a matter of right within 2 months from the mailing date of the Examiner's Answer or Supplemental Examiner's Answer. The two month period for responding to the Reply Brief will expire on January 30, 2008.

Appellant responds to the Examiner's Answer as follows:

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

Neither appellant nor the Examiner are aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The Examiner agrees that the appellant's statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The Examiner agrees that the appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The Examiner agrees that the appellant's summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The Examiner agrees that the appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The Examiner agrees that the appellant's copy of the appealed claims contained in the Appendix to the brief is correct. A further copy of the appealed claims is contained in the Appendix attached with this Reply Brief for the convenience of the Board.

(8) Evidence Relied Upon

The Examiner has relied upon US Patent No. 5,951,539 Nita, et al. (hereinafter, "Nita"), US Patent Application Publication No. 2003/0109851 to Landuyt (hereinafter, "Landuyt"), and US Patent No. 5728065 to Follmer, et al. (hereinafter, " Follmer").

(9) Grounds of Rejection

Claims 1, 3, 6-11, 24, 25-28, 41, 46-53, 56-61, and 63-65 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Nita.

Claims 1, 3, 6-11, 24, 26-28, 41, 43, 46-53, 56-61, and 63-65 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Nita in view of Landuyt.

Claims 4, 5, 44, 45, 54, and 55 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Nita as applied to claims 1, 41, and 52, and further in view of Follmer.

Claims 4, 5, 44, 45, 54, and 55 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Nita in view of Landuyt as applied to claims 1, 41, and 52, and further in view of Follmer.

The Examiner's Answer of November 30, 2007 contained no new grounds of rejection under 37 C.F.R. § 41.39(b) but it did contain additional information in the form of a reproduction of Figure 5 of Nita with additional markings provided by the Examiner, apparently presented in an attempt to support the Examiner's interpretation of the primary prior art reference of Nita. The Examiner's Answer also contained clarifications and a refocus of earlier positions taken during prosecution. Appellant responds to this new information below.

Coil Reinforcement Member – The Examiner's Marked-Up Drawing

First, it is respectfully submitted that none of the drawings of Nita support the Examiner's position that the coil reinforcement member:

i) extends from the proximal end of the catheter and terminates at the second end of the tubular member, the second end defining a distal end of the catheter (claim 1);

ii) extends from the lead end of the catheter stock to the trailing end of the catheter stock entirely (claim 24);

iii) extends from the first end of the tubular member and terminates at the second end of the tubular member (claim 41);

iv) is carried on a tubular member and terminates at the first and second ends of the tubular member (claim 52);

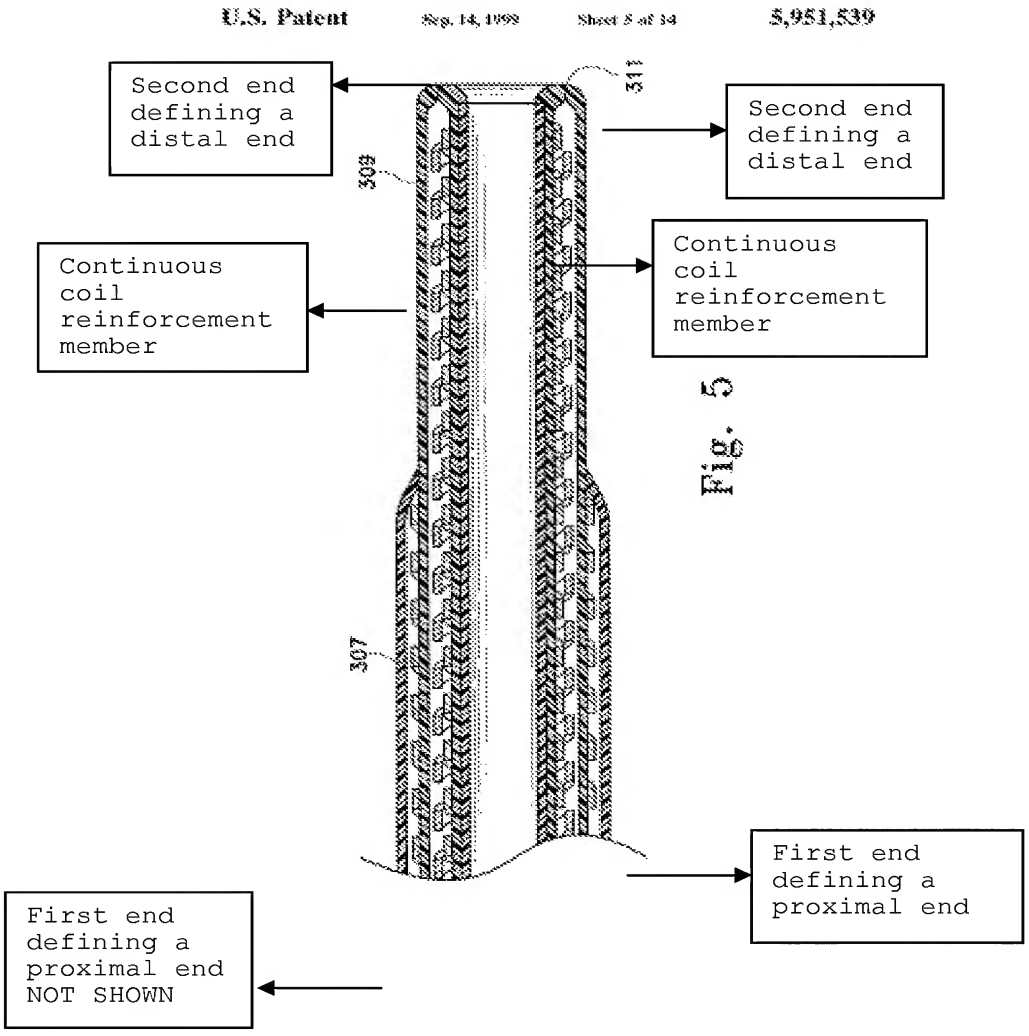
v) extends in the distal tip of the catheter completely to the second end of the tubular member which defines the distal end of the catheter (claim 61); or

vi) is on a tubular member and extends completely to and terminates at the second end of the tubular member (claim 65).

Rather, the coil reinforcement member as disclosed in Nita is carried in the catheter along the length thereof. It extends to a point near the distal end of the catheter but not to a point fully at the distal end. Essentially, in each of the embodiments of the catheter taught in Nita, some amount of catheter body not containing the coil reinforcement member is present at the tip area.

The Examiner attempted to demonstrate her argument that the coil member in Nita extended to the distal (second) end of the catheter and to the proximal (first) end by providing into the record a marked-up version of Figure 5 of Nita. However, appellants respectfully submit that the Examiner's marked-up figure actually supports

appellant's position, rather than the Examiner's position. To illustrate, appellant presents the Examiner's marked up Figure 5 together with additional markings which show along the left side thereof, the proper extent of the distal (second) end of the catheter and to the proximal (first) end of the catheter. As can be seen, the coil reinforcement member in the Nita catheter does not extend fully to the distal end of the catheter. Rather, a distal nose tip section is formed on the end of the catheter in an area between the Examiner's "end" and appellant's end as so marked.



Per Applicant Per Examiner

Next, the Examiner seeks to "remove" the small amount of area of catheter in Nita in the area between the terminal end of the coil reinforcement member and the terminal end of the overall catheter body by misinterpreting column 15, lines 7-11 of Nita. Taken out of context, this portion of Nita is, at best, confusing. However, when read in the light of the specification of Nita it is clear that the applicants there were describing the independence of the "use of layers of coil in excess of the preferred dual layer" relative to other features of the catheter. Column 15, lines 7-11 of Nita do not at all teach or suggest, as the Examiner would argue, "that the distal nose tip section may not be present in the embodiment shown in Figure 5 or in the other figures." Rather, that portion of Nita, when properly read in context, means that the use of additional coil layers is a feature independent of the presence or absence of other features, e.g., the ***particular/specific*** distal nose tip section (311), shown in this Figure or ***the particular/specific distal nose tip sections shown in*** other Figures. (emphasis added). The applicants in Nita wanted to be sure to not restrict the use of the additional coil layers on catheters of the type having the distal nose section as shown in Figure 5, but to extend its use to all of the disclosed catheters, regardless of the particular distal nose tip section (or any other feature) present. Again, appellants respectfully submit that the distal nose tip section is present in each of the embodiments of Nita.

The Examiner cites Figure 10 of Nita in support of her argument that the catheter has "a continuous coil reinforcement member which extends from the proximal end of the catheter and terminates at the second or distal end" of the catheter. However, as previously stated by appellant, Figure 10 of Nita "shows, in cross-section, a desirable intermediate section" (emphasis added) of the catheter as

noted at column 8, lines 32 and 33 of Nita. Simply, Figure 10 of Nita shows neither a proximal end of a catheter nor a distal end of a catheter.

Next in the Examiner's Answer, the Examiner concedes at the top of page 5 that Figure 10 of Nita actually does show an intermediate section of a catheter, but then she takes the position, without any basis, that the catheter "may have a distal section such as those shown in Figures 7, 11, or 12." However, upon simple inspection of Figures 7, 11, or 12 it is clear that the coil reinforcement member stops short of extending fully to the distal end of the catheter. Appellant respectfully refers the Board to the marked up drawing above whereat appellant has noted the distal end of the catheter. A comparison between the marked up Figure 10 in this Reply Brief and Figures 7, 11, or 12 cited by the Examiner shows that the coil reinforcement member of Nita stops short of extending fully to the distal end of the catheter.

SHORE Hardness of Layers/Materials

The Examiner conceded that Nita is silent on the specifics of the first coating being softer that the second coating. Appellants agree. However, appellants do not agree with other positions taken by the Examiner including that:

i) it would have been obvious to choose a harder material for the second coating of the catheter of Nita because, according to the Examiner, Nita teaches choosing the material of the second coating so that the portion of the catheter with the second coating would be stiffer than the portion without the second coating; and

ii) as to the specific hardness of the first and outer coatings, the parameter of hardness is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

In support of the above, the Examiner cited column 14, lines 36-56 and column 16, lines 7-18 of Nita.

As a threshold point, appellant respectfully submits that the first disclosure portion in Nita at column 14, lines 36-56 cannot be combined in the manner as suggested by the Examiner with the second disclosure portion at column 16, lines 7-18. More particularly, appellant traverses the Examiner contention that "when the first outer coating (546) has a Shore hardness of 40D, the material of the second outer coating (542) could be chosen to have a Shore hardness of 70D to provide additional stiffness in that proximal section." Column 14, lines 36-56 clearly refer to Figure 3D which teaches four (4) axially arranged regions of a polymer outer covering. These four regions collectively form a second or outer coating covering a first or inner layer 202 (shown in Figures 3A-3C) apparently to provide a flexibility characteristic to the catheter that varies in an axial direction. The disclosure in Nita describing the construction of the catheter in Figure 3D only teaches a relatedness of hardness between adjacent axially arranged second layers of outer coatings 240, 242, 244, 246 in an axial direction along the length of the catheter. It makes no reference and does not teach in any way a connection or dependence of the hardness between inner and outer layers of coatings, i.e., in a radial direction. Column 14, lines 36-56 of Nita never mentions the inner layer 202. It is discussed in connection with Figure 3A as being simply an "interlubricious layer" and it is shown without specifying any particular properties, namely, its hardness measure. Appellants respectfully submit, therefore, that Nita does not recognize controlling properties of a catheter by selecting the hardness of inner and outer layers thereof – a feature of each of the claims herein on Appeal.

The Examiner cites to column 16, lines 7-18 of Nita. This portion clearly refers to Figure 10 which teaches a single additional outer coating 542 in a radial direction "to provide additional stiffness to that section" (lines 13, 14). It is simple physics that adding a fourth layer 542 onto the third layer 546 of a catheter will make that portion of the catheter stiffer in that section. Adding a fifth layer (not shown) onto the fourth layer 546 would make that portion even more stiff. However, column 16, lines 7-18 of Nita referred to by the Examiner never teaches or suggests a relation between the hardness of the inner and outer layers – or the relative hardness between any of the layers. That portion of Nita only notes that such an outer layer (542, Fig. 10) "may be of a wide variety of material chosen either to enhance the lubricity of the overall catheter assembly or to provide additional stiffness to that section." Again, it is respectfully submitted that it falls short of disclosing that the selection of the material of the outer layer bears any relationship with the selection of the material forming the inner layer. In each of claims 1, 24, 41, 52, 61, and 65, the first coating is softer than said second coating.

Obviousness/Examination Guidelines

Yet another reason as to why the present rejection is deficient and must be withdrawn, relates to the recently issued "Examination Guidelines for Determining Obviousness Under 35 USC 103 In View of the Supreme Court Decision in *KSR International Co. v. Teleflex*," published in the Federal Register, Vol. 72, No. 195, Oct. 10, 2007.[1] As explained in those guidelines, the Supreme Court stated that "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning

[1] The Guidelines state that they are effective October 10, 2007.

to support the legal conclusion of obviousness." Fed Reg. 57528-57529, citing *KSR*, 550 US at ___, 82 USPQ2d at 1396. One of the accepted rationales, and one which the Examiner apparently relies upon, is "obvious to try."

Specifically, the Examiner conceded on page 6 of the Examiner's Answer that "Nita et al are silent on the specifics of the first coating being softer than the second coating" but then argued that it would have been obvious to one having ordinary skill in the art "to choose a harder material for the second coating of the catheter" because "Nita et al teach choosing the material of the second coating so that the portion of the catheter with the second coating would be stiffer than the portion without the second coating." The Examiner further argued that "Nita et al teach using softer coatings on the distal portions of the catheter where more flexibility would be advantageous and using the harder coatings on the proximal sections to provide the desired stiffness to those sections."

As to the first contention, again, simple physics dictates that a portion of the catheter with a second coating i.e. a "two-layered catheter" would be stiffer than the portion without a second coating i.e. a "single layer" catheter. Choosing to add a second layer where there was none does not teach or suggest choosing specific hardness of layers. Therefore, the Examiner seems to be arguing that it would be obvious to try selecting materials of different hardness for inner and outer layers when one chooses to add an additional layer.

As to the Examiner's second contention that it would be advantageous to use harder coatings on the proximal sections of a catheter to provide the desired stiffness to those sections because Nita et al teach "using softer coatings on the distal portions of the catheter", it is respectfully submitted that Nita teach selecting hardness of the material between adjacent axially arranged outer layers, and are

silent on selecting the hardness of inner and outer layers as in the claims on Appeal. Therefore, the Examiner seems to be arguing that it would be obvious to try selecting materials of different hardness for the inner layer when adding axially arranged outer layers having specific hardness properties.

The Examination Guidelines then describe specific findings that the Examiner must make in order to properly reject claims under this rationale of "obvious to try":

> To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Office personnel must then articulate the following:
>
> (1) a finding that at the time of the invention, there had been a recognized problem or need in the art, which may include a design need or market pressure to solve a problem;
>
> (2) a finding that that there had been a finite number of identified, predictable potential solutions to the recognized need or problem;
>
> (3) a finding that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success; and
>
> (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The Guidelines continue and state that:

> If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Federal Register at 57532.

These Guidelines became effective on October 10, 2007. The Examiner's Answer was prepared on October 20 and mailed on October 30, 2007. However, the Examiner did not follow the Guidelines and, in particular, did not apply any of the obviousness factors set out above.

Appellant does not concede that it would be obvious to try to use an inner layer in the catheter of Nita having a hardness property selected based on the hardness of the outer layer. Particularly, it would not be obvious to use a softer inner layer (relative to the outer layer) in a catheter having a coil reinforcement member therein.

The claims were also rejected as being unpatentable over Nita in view of Landuyt. Still further, the claims were rejected as being unpatentable over Nita/Landuyt, and further in view of Follmer. Also, the claims were rejected as being unpatentable over Nita in view of Landuyt, and further in view of Follmer.

The Examination Guidelines also describe specific findings that the Examiner must make in order to properly reject claims under this rationale of "combining prior art elements according to known methods to yield predictable results":

> To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Office personnel must then articulate the following:
>
> (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference;
>
> (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately;
>
> (3) a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable; and
>
> (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The Guidelines continue and state that:

> If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Federal Register at 57532.

Regarding the first factor, the Examiner has not at all demonstrated that the only difference between the claimed invention and the prior art is the lack of actual combination of the elements in a single prior art reference. Here, the Examiner's proposed combinations of prior teachings would result in significant differences between the claims and the combination. Regarding the second factor, the Examiner has not at all demonstrated that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination,

each element merely would have performed the same function as it did separately. Here the Examiner's suggested combination seeks to merge catheters having a coil reinforcement member together with catheters without such elements. Also, regarding the third factor, the Examiner has not at all demonstrated that one of ordinary skill in the art would have recognized that the results of the combination were predictable. As argued earlier by appellants, the Nita patent does not recognize selecting the hardness of the inner and outer layers of the catheter for a desired result and Landuyt does not teach or suggest a catheter having a construction including a coil reinforcement member.

CONCLUSION

It is respectfully submitted that the Examiner has not made out a case of anticipation with regard to the claims pending in the instant application for reasons set out above and as set out during prosecution and in the Appeal Brief. In light of the foregoing, it is respectfully submitted that the present application is in a condition for allowance and notice to that effect is hereby requested.

Allowance of all pending claims and early notice to that effect is requested.

If there are any additional fees resulting from this communication, please charge same to our Deposit Account No. 18-0160, our Order No. ANG-17553.

Respectfully submitted,

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APPENDICES

(11) Related Proceeding(s)

No decision rendered by a court or the Board was identified by the Examiner in the Related appeals and Interferences section of this Examiner's answer.

(12) Claims Appendix

Claims involved in the Appeal are as follows:

1. (Previously Presented) A reinforced catheter comprising:

an elongate flexible tubular member defining a lumen of the catheter, the tubular member having a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter;

a continuous coil reinforcement member carried on the elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the tubular member;

a first flexible outer coating covering the coil reinforcement member and the tubular member substantially entirely between the proximal end of the catheter and the distal end of the catheter; and,

a second flexible outer coating covering a first portion of the first outer coating between a first transition area of the catheter and said proximal end of the catheter, a second portion of the first outer coating between said first transition area and said distal end of the catheter being uncovered by said second outer coating and defining a flexible distal tip of said catheter, the first coating being softer than said second coating.

2. (Canceled)

3. (Previously Presented) The reinforced catheter according to claim 1 wherein:

said first flexible outer coating has a Shore hardness of about 40D; and,

said second flexible outer coating has a Shore hardness of about 70D.

4. (Previously Presented) The reinforced catheter according to claim 1, further comprising a marker band disposed adjacent the distal end of the catheter on the first flexible outer coating.

5. (Original) The reinforced catheter according to claim 4, wherein the marker band is formed of a one of gold material and platinum material.

6. (Original) The reinforced catheter according to claim 1, wherein the elongate flexible tubular member is formed of a polytetrafluoroethylene (PTFE) material.

7. (Original) The reinforced catheter according to claim 1, wherein the continuous coil reinforcement member is a stainless steel wire.

8. (Original) The reinforced catheter according to claim 1, wherein the continuous coil reinforcement member defines a helical pattern.

9. (Original) The reinforced catheter according to claim 1, wherein a thickness of the distal end of the catheter is less than a thickness of the proximal end of the catheter.

10. (Original) The reinforced catheter according to claim 1, wherein the first outer coating is comprised of one of a group of materials consisting of nylon material and urethane material.

11. (Original) The reinforced catheter according to claim 1, wherein the second outer coating is comprised of a nylon material.

12. (Withdrawn) A method of manufacturing multiple reinforced catheters comprising the steps of:

providing a selected length of an elongate cylindrical tube carried on opposite first and second spool members with a portion of the cylindrical tube extending between the first and second spool members;

providing a selected length of a reinforcement wire;

for substantially the length of the cylindrical tube, advancing the cylindrical tube from the first spool member to the second spool member while simultaneously wrapping the reinforcement wire onto said portion of the cylindrical tube between the first and second spool members to form a continuous length of reinforced catheter stock;

coating the reinforced catheter stock with a predetermined thickness of a first coating and followed by a second coating harder than said first coating for substantially the length of the cylindrical tube to form a continuous length of coated catheter stock; and,

cutting the coated catheter stock at selected locations corresponding to desired catheter lengths to form a plurality of reinforced catheters.

13. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 12 further including the step of grinding the second coating of any one or more of said plurality of reinforced catheters to expose a portion of the first coating and to provide a desired outer surface finish and a desired flexibility along the longitudinal length of the catheter.

14. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 13 further including the step of swaging a marker band around the outer surface of the coating at a distal end of the any one or more of said plurality of reinforced catheters.

15. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 14, wherein the step of swaging the marker band includes swaging a marker band formed of one of a group of materials consisting of gold and platinum.

16. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 14, wherein the grinding step includes grinding a portion of the catheter beginning at a first end defining a distal end of the catheter for a predetermined distance along the longitudinal length of the catheter toward a second end defining a proximate end of the catheter.

17. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 16, wherein the grinding step includes grinding the portion of the

catheter such that the thickness of the finish coating at the distal end of the catheter is less than the thickness of the finish coating at the proximate end of the catheter.

18. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 17, further including the step of coating a ground portion of the catheter with a predetermined thickness of a soft finish coating.

19. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 18, wherein the step of coating the ground portion with said soft finish coating includes coating the ground portion with a urethane material.

20. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 12, wherein the cylindrical tube is a polytetrafluoroethylene (PTFE) material.

21. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 12, wherein the reinforcement wire is a stainless steel wire.

22. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 12, wherein the wrapping step includes wrapping said reinforcement wire onto said cylindrical tube in a helical pattern.

23. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 12, wherein the coating step includes coating the reinforced catheter stock with a predetermined thickness of said first coating followed by a

predetermined thickness of said second coating, the first coating having a Shore hardness of about 40D and said second coating having a Shore hardness of about 70D.

24. (Previously Presented) A reinforced catheter stock for manufacturing reinforced catheters, the catheter stock comprising:

a selected length of an elongate flexible tubular member defining a lumen of the catheter stock, the tubular member having a first end defining a lead end of the catheter stock and a second end defining a trailing end of the catheter stock;

a continuous coil reinforcement member carried on the elongate flexible tubular member and extending from the lead end of the catheter stock to the trailing end of the catheter stock entirely;

a continuous outer coating of a first material covering the coil reinforcement member and the tubular member substantially entirely between said lead end of the catheter stock and the trailing end of the catheter stock; and,

a continuous outer coating of a second material covering said continuous outer coating of said first material substantially entirely between said lead end of the catheter stock and the trailing end of the catheter stock, said first material being softer than said second material.

25. (Canceled)

26. (Previously Presented) The reinforced catheter stock according to claim 24, wherein:

the continuous coil reinforcement member defines a helical pattern;

the first material has a Shore hardness of about 40D; and,

the second material has a Shore hardness of about 70D.

27. (Original) The reinforced catheter stock according to claim 24, wherein the elongate flexible tubular member is a polytetrafluoroethylene (PTFE) material.

28. (Original) The reinforced catheter stock according to claim 24, wherein the continuous coil reinforcement member is a stainless steel wire.

29. (Withdrawn) A method of manufacturing a reinforced catheter stock, the method comprising the steps of:

providing a selected length of an elongate cylindrical tube carried on opposite first and second spool members with a portion of the cylindrical tube extending between the first and second spool members;

providing a selected length of a reinforcement wire; and

while advancing the cylindrical tube from the first spool member to the second spool member, wrapping the reinforcement wire onto the cylindrical tube at a point between the first and second spool members for substantially the length of the cylindrical tube to form a continuous length of reinforced catheter stock.

30. (Withdrawn) The method of manufacturing reinforced catheter stock according to claim 27, further comprising the step of coating the reinforced catheter stock with a predetermined thickness of a first finish coating then a second finish coating harder than said first finish coating for substantially the length of the cylindrical tube to form a continuous length of coated catheter stock.

31. (Withdrawn) The method of manufacturing reinforced catheter stock according to claim 29, wherein the step of providing said elongate cylindrical tube includes providing a polytetrafluoroethylene (PTFE) material.

32. (Withdrawn) The method of manufacturing reinforced catheter stock according to claim 29, wherein the step of providing said selected length of said reinforcement wire includes providing stainless steel wire.

33. (Withdrawn) The method of manufacturing reinforced catheter stock according to claim 29, wherein the wrapping step includes wrapping said reinforcement wire onto said cylindrical tube in a helical form.

34. (Withdrawn) An apparatus for manufacturing reinforced catheter stock, the apparatus comprising:

a first support member and a second support member, the first and second support members being spaced apart and carrying an elongate cylindrical tube with a portion of the cylindrical tube extending between the first support member and the second support member;

a winder device carrying a selected length of a reinforcement member, the winder device being adapted to wind the reinforcement member onto the cylindrical tube at a point between the first and second support members; and,

a control device simultaneously controlling i) advancement of the cylindrical tube relative to the winder device and ii) winding the reinforcement member onto

said cylindrical tube by the winder device at the point between the first and second support members.

35. (Withdrawn) The apparatus according to claim 34, wherein said first support member includes a pay-out spool and said second support member includes a take-up spool, the pay-out spool and the take-up spool being responsive to the control device to pay out the elongate cylindrical tube from the pay-out spool and onto the take-up spool.

36. (Withdrawn) The apparatus according to claim 34, wherein the elongate cylindrical tube is a polytetrafluoroethylene (PTFE) material.

37. (Withdrawn) The apparatus according to claim 34, wherein the winder device includes:

a coiler tip member defining i) a central bore adapted to receive said cylindrical tube at the point between the pair of spaced apart support members, and ii) an offset opening carrying said reinforcement member, the coiler tip member being selectively rotatable relative to said cylindrical tube to wind the reinforcement member onto the cylindrical tube at selected varied angles relative to a plane perpendicular to a longitudinal axis of the cylindrical tube.

38. (Withdrawn) The apparatus according to claim 37, wherein the winder device further includes:

a motor for rotating the coiler tip member relative to the cylindrical tube;

a spool for carrying the reinforcement member; and,

a tubular member adapted to rotate with the coiler tip member to feed the reinforcement member from said spool and through the offset opening of the coiler tip member as the reinforcement member is wound onto the cylindrical tube.

39. (Withdrawn) The apparatus according to claim 38, wherein the winder device is adapted to wind the reinforcement member onto the cylindrical tube in a helical pattern.

40. (Withdrawn) The apparatus according to claim 34, wherein the reinforcement member is comprised of a stainless steel wire.

41. (Previously Presented) A reinforced catheter comprising:

an elongate flexible tubular member defining a lumen of the catheter, the tubular member having a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter;

a first flexible outer coating covering the tubular member fully between the proximal end of the catheter to the distal end of the catheter;

a second flexible outer coating covering a first portion of the first outer coating at said proximal end of the catheter, a second portion of the first outer coating being uncovered by said second outer coating at said distal end of the catheter and defining a flexible distal tip of said catheter, the first coating being softer than said second coating; and,

a coil reinforcement member carried on the elongate flexible tubular member and extending from said first end of the tubular member and terminates at said second end of the tubular member.

42. (Canceled)

43. (Previously Presented) The reinforced catheter according to claim 41 wherein:

said first flexible outer coating has a Shore hardness of about 40D; and,

said second flexible outer coating has a Shore hardness of about 70D.

44. (Previously Presented) The reinforced catheter according to claim 41, further comprising a marker band disposed adjacent the distal end of the catheter on the first flexible outer coating.

45. (Previously Presented) The reinforced catheter according to claim 44, wherein the marker band is formed of a one of gold material and platinum material.

46. (Previously Presented) The reinforced catheter according to claim 41, wherein the elongate flexible tubular member is formed of a polytetrafluoroethylene (PTFE) material.

47. (Previously Presented) The reinforced catheter according to claim 41, wherein the coil reinforcement member is a stainless steel wire.

48. (Previously Presented) The reinforced catheter according to claim 41, wherein the coil reinforcement member defines a helical pattern.

49. (Previously Presented) The reinforced catheter according to claim 41, wherein a thickness of the distal end of the catheter is less than a thickness of the proximal end of the catheter.

50. (Previously Presented) The reinforced catheter according to claim 41, wherein the first outer coating is comprised of one of a group of materials consisting of nylon material and urethane material.

51. (Previously Presented) The reinforced catheter according to claim 41, wherein the second outer coating is comprised of a nylon material.

52. (Previously Presented) A reinforced catheter comprising:

an elongate flexible tubular member having first and second ends and defining a lumen of the catheter;

a continuous coil reinforcement member on the elongate flexible tubular member and terminating at said first and second ends of the tubular member;

a first flexible outer coating covering the coil reinforcement member and the tubular member substantially entirely between the first end and the second end of the tubular member; and,

a second flexible outer coating covering a first portion of the first outer coating from a first transition area of the catheter and terminating at said first end of tubular member, a second portion of the first outer coating being uncovered by said second outer coating and defining a flexible distal tip of said catheter from said first transition area and terminating at said second end of the tubular member, the first coating being softer than said second coating.

53. (Previously Presented) The reinforced catheter according to claim 52 wherein:

said first flexible outer coating has a Shore hardness of about 40D; and,

said second flexible outer coating has a Shore hardness of about 70D.

54. (Previously Presented) The reinforced catheter according to claim 52, further comprising a marker band disposed adjacent the second end of the tubular member on the first flexible outer coating.

55. (Previously Presented) The reinforced catheter according to claim 54, wherein the marker band is formed of a one of gold material and platinum material.

56. (Previously Presented) The reinforced catheter according to claim 52, wherein the elongate flexible tubular member is formed of a polytetrafluoroethylene (PTFE) material.

57. (Previously Presented) The reinforced catheter according to claim 52, wherein the continuous coil reinforcement member is a stainless steel wire.

58. (Previously Presented) The reinforced catheter according to claim 52, wherein the continuous coil reinforcement member defines a helical pattern.

59. (Previously Presented) The reinforced catheter according to claim 52, wherein the first outer coating is comprised of one of a group of materials consisting of nylon material and urethane material.

60. (Previously Presented) The reinforced catheter according to claim 52, wherein the second outer coating is comprised of a nylon material.

61. (Previously Presented) A reinforced catheter comprising:

an elongate flexible tubular member defining a lumen of the catheter, the tubular member having a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter;

a first flexible outer coating covering the tubular member completely from the distal end of the catheter to the proximal end of the catheter;

a second flexible outer coating covering a first portion of the first outer coating at the proximal end of the catheter, a second portion of the first outer coating at the distal end of the catheter being uncovered by said second outer coating and defining a flexible distal tip of said catheter, the first coating being softer than said second coating; and,

a coil reinforcement member carried on the elongate flexible tubular member and extending in said distal tip of the catheter completely to said second end.

62. (Canceled)

63. (Previously Presented) The reinforced catheter according to claim 61, wherein said coil reinforcement member terminates at said first end of said tubular member.

64. (Previously Presented) The reinforced catheter according to claim 63, wherein:

said first flexible outer coating has a Shore hardness of about 40D; and,

said second flexible outer coating has a Shore hardness of about 70D.

65. (Previously Presented) A reinforced catheter comprising:

an elongate flexible tubular member having first and second ends and defining a lumen of the catheter;

a continuous coil reinforcement member on the elongate flexible tubular member and extending completely to and terminating at said second end of the tubular member;

a first flexible outer coating covering the coil reinforcement member and the tubular member substantially entirely between the first end and the second end of the tubular member; and,

a second flexible outer coating covering a first portion of the first outer coating from a first transition area of the catheter and terminating at said first end of the tubular member, a second portion of the first outer coating being uncovered by said second outer coating and defining a flexible distal tip of the catheter from said first transition area and terminating at said second end of the tubular member, the first coating being softer than said second coating.